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*From the Office of the President*

October 14, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852

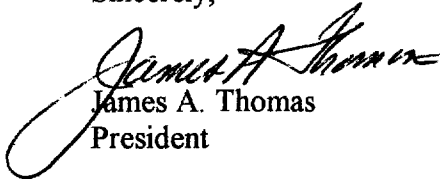
To Whom It May Concern:

We are writing in response to a notice in the Federal Register of Friday, July 30, 1999 regarding a Proposed Rule to Reclassify Surgeon's and Patient Examination Gloves.

Members of ASTM Committee D11 on Rubber have carefully reviewed the proposed rule and provide the comments on the attached letter.

Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in cursive script, appearing to read 'James A. Thomas', written over the printed name and title.  
James A. Thomas  
President

CC: D11 Executive Committee  
D11.40 Subcommittee

98N-0313

C11



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### **Committee D11 on RUBBER**

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**Subject:** Surgeon's and Patient Examination Gloves; Reclassification  
21 CFR Parts 801, 878, and 880  
Docket Number 98N - 0313  
RIN 0910 - AB74

ASTM is a not-for-profit organization that provides a forum for producers, users, ultimate consumers, and those having a general interest (representatives of government and academia) to meet on common ground and write consensus standards for materials, products, systems, and services.

The National Technology Transfer and Advancement Act (P. L 104-113) and the Office of Management and Budget (OMB) Circular A-119 direct the FDA to use voluntary consensus standards. These documents instruct government agencies to help business speed new products and bring new technology to the marketplace, to provide cost savings by discouraging duplicative efforts on the part of the government, and to encourage federal agencies to benefit from the experience of the private sector. Under the Act, "all federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments."

On October 16, 1997, Donald E. Marlowe, FDA CDRH, wrote a letter to the chairman of ASTM D11.40 on Consumer Rubber Products inviting ASTM to "...develop standards for the maximum water-soluble protein and the maximum allowable amount of the combination of donning powder and former-release agents on natural latex or natural rubber medical devices..." As a result of this request, two working groups under the D11.40 subcommittee were formed: the Maximum Latex Protein Working Group and the Maximum Powder Working Group. These two working groups whose constituents include: users, consumers, manufacturers, as well as 8 representatives from the FDA have convened a total of 20 meetings throughout the country over the past 2 years to discuss the maximum levels of protein and powder. Numerous working group members

have spent valuable time and money attending these 20 meetings. Members of the working groups have prepared protocols for round robin testing, participated in the round robins, and analyzed the results to determine a path forward.

Due to the effort of these the two working groups and the D11.40 subcommittee, ASTM has approved and published the following standards: D3577-99, D3578-99, D5250-99, D5712-99, and D6124-97. During the development process, the FDA voted affirmatively on the recommended protein limit in approved standards D3577-99 and D3578-99. The FDA further voted affirmatively on the limit of powder residue in approved standards D3577-99, D3578-99, D5250-99, and D6124-97.

Published ASTM standards D3577-99, D3578-99, and D5250-99, each provide that the powder residue per glove shall not be more than 4.0 milligrams per glove for the year after these standards were published, 3.0 milligrams for the following year and 2.0 milligrams thereafter. The FDA proposes a standard of 2.0 milligrams per glove. Assuming that the FDA rule does not go into effect prior to the ASTM standards reaching 2.0 milligrams, these requirements are consistent with each other.

ASTM thanks the FDA for their participation in the development of the recommended protein and powder residue limits in the revised ASTM standards, and ASTM strongly urges the FDA use the limits agreed upon in these standards.

The Federal Register poses 12 specific questions to be commented on and ASTM wishes to comment on the following:

7. Recommended protein limit of 1200 ug:

FDA proposes a recommended residual protein limit of no more than 1200 micrograms of extractable protein per glove.

Currently published ASTM standard specifications for medical gloves recommended a maximum residual protein limit of 200 micrograms (ug) per square decimeter (dm<sup>2</sup>). During the development of this residual protein limit, ASTM considered a protein limit on a per glove basis, but rejected the approach since it was considered impractical and confusing. A limit based on a single glove was considered impractical because (1) gloves of different sizes, but containing the same amount of protein in micrograms per gram, would have different protein values depending on the size of the gloves, i.e., small versus extra-large, (2) the typically understood less than 50 ug per gram lower limit label would be changed to different numeric values depending on the size of the glove, e.g., small glove: 50 ug/g x 6 g glove = 300 ug/glove; large glove: 50 ug/g x 10 g glove = 500 ug/glove) and this could be confusing to the consumer, and (3) of the need for an orderly transition from current glove production processes and protein monitoring to those able to achieve lower residual levels of protein. Moreover, ASTM's use of surface area units instead of glove units maintains the numeric equivalency between protein values per gram (weight units) and values per dm<sup>2</sup> (area units). For example, the current protein content label of 50 ug/g approximates 50 ug/dm<sup>2</sup>, and the 200 ug/g value approximates 200 ug/dm<sup>2</sup>. Whereas an FDA revised label of 300 ug/glove is numerically inconsistent with the current 50 ug/g label. A revision of this kind would be confusing to the consumer that is already familiar with the current numeric values and labeling of residual protein on gloves.

ASTM has two currently approved standards for surgical and examination gloves (D3577-99 and D3578-99, respectively) with a recommended aqueous soluble protein limit of 200 micrograms per decimeter squared surface area. It is ASTM's position that the proposed FDA protein limit is inconsistent with the voluntary consensus standards ASTM D3577-99 and D3578-99 for medical gloves, and impractical and confusing for both the manufacturer and the consumer. Therefore, ASTM urges the FDA to amend their proposal so that it is consistent with that of ASTM standards, which the agency helped to develop and recognizes as consensus standards.

9. Recommended limits versus required limits:

ASTM would like to point out that currently published standards D3577-99 and D3578-99 define the limit on protein as recommended not required. It was adopted in this form because, as stated in Annex A2 to standards D3577-99 and D3578-99, consideration must be given to the relative repeatability and reproducibility when reporting test method results. Similarly, it is recommended that the FDA limit for protein content be only recommended limits until greater assay precision can be achieved.

10. Shelf Life protocols

ASTM has formed a new Task Group on Expiration Dating for Medical Gloves under D11.40 on Consumer Rubber Products. This task group will develop a guidance document for expiration dating for medical gloves. The task group will meet in December to begin the review of the first draft of the guidance document.

Sincerely,

Kok-Kei Hon

Kok-Kee Hon  
D11.40 Chairman

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